

**REMARKS**

The Office Action mailed May 25, 206, has been received and reviewed. Claims 12, 18, 22-24, 27, and 28 are currently under examination in the application. Claims 12, 18, and 22-24 stand rejected. Claims 12, 22, 27, and 28 are objected to. Claims 1-11, 13, 14, 19-21, 25, and 26 are withdrawn from consideration. Claims 15-17 were cancelled without prejudice or disclaimer. No new matter has been added.

Reconsideration of the application is respectfully requested.

**Claim Objections**

Claims 12 and 22 are objected to for grammatical reasons. Claims 12 and 22 have been amended as suggested in the Office Action, changing "an altered" to "an alteration of the". Reconsideration and withdrawal of the objection are respectfully requested.

Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Applicant thanks the Examiner for indicating the allowability of the claims, and the claims have been rewritten into independent form including all of the elements of the base claim and any intervening claim. Therefore, at least claims 27 and 28 should be in condition for allowance.

**Double patenting rejection**

Claims 12, 18, and 22-24 stand rejected under the judicially created doctrine of obviousness-type double patenting ("ODP") as allegedly being unpatentable over claims 1, 2, 4, 6, 8, 10, 11, and 13 of U.S. Patent 5,948,763 (hereinafter the '763 patent) in view of Findeis *et al.* (WO 96/28471). Applicant respectfully traverses the rejection as hereinafter set forth.

Applicant respectfully submits that the ODP rejection is improper as the '763 patent issued (September 7, 1999) prior to the earliest claimed priority date of the present application (November 5, 1999). "In analyzing cases of [ODP], it must always be carefully observed that the . . . patent is not 'prior art' under either section 102 or under section 103." *In re Boylan*, 392 F.2d 1017, 1018 (CCPA 1968). Consequently, applicant respectfully submits that '763 patent cannot form the basis of an ODP rejection because it qualifies as prior art at least in that the patent was granted before the earliest effective filing date of the present application. As such,

applicant respectfully requests the withdrawal of the ODP rejection of claims 12, 18, and 22-24, and reconsideration of same.

Further, applicant respectfully submits that claims 12, 18, and 22-24 are allowable over claims 1, 2, 4, 6, 8, 10, 11, and 13 of the '763 patent in view of Findeis *et al.*

Claims 12, 18, and 22-24 recite, in part, a  $\beta$ -sheet breaker peptide analog which is generated by chemical modification of the  $\beta$ -sheet breaker peptide of SEQ ID NO: 1. However, neither claims 1, 2, 4, 6, 8, 10, 11, and 13 of the '763 patent, or Findeis *et al.*, teach or suggest, either alone or in combination, the superiority of the claimed sequence or that the claimed chemical modifications would increase stability, particularly, since the mechanism of degradation was unknown at the time (*see*, para. 63 of the specification). Therefore, only through the use of impermissible hindsight may a person of ordinary skill in the art identify the desirability of the presently claimed sequence and the claimed chemical modifications.

Without the aid of the applicant's specification, a person of ordinary skill in the art is provided no motivation by claims 1, 2, 4, 6, 8, 10, 11, and 13 of the '763 patent to identify the presently claimed sequence, chemically modify that sequence, or a reasonable expectation that the modifications would increase stability *in vivo* and retain *in vivo* function. The Office concedes that claims 1, 2, 4, 6, 8, 10, 11, and 13 of the '763 patent do "not teach that the inhibiting peptide is chemically modified" (page 4 of the Office Action). Further, Findeis *et al.* does not teach or suggest that chemical modification of the claimed sequence would increase stability without compromising the function *in vivo*. Hence, there is no motivation to combine the cited references. While the present application, for the first time, demonstrates that a person of ordinary skill in the art could have selected the appropriate peptide and then could have selected the claimed modifications, the proper test for obviousness is whether a person of ordinary skill in the art, at the time of filing, would have selected the claimed peptide sequence and would have been motivated to apply the claimed modifications, and, finally, would have had a reasonable expectation that the  $\beta$  sheet breaker peptide analog would not lose *in vivo* activity and would have increased stability. Since, only the present specification provides *in vivo* data demonstrating that chemical modification of SEQ ID NO: 1 produces a product having increased stability and retaining activity *in vivo*, the person of ordinary skill in the art did not have the motivation to identify the present sequence and would not have had a reasonable expectation of

success. They simply would not know whether the claimed sequence and modifications would have increased stability until the modifications were tested *in vivo*.

It is also noted that in an ODP rejection, "[w]hen considering whether the invention defined in a claim of an application ... would have been ... an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art (MPEP § 804(II)(B)(1), *citing General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). Claims 1, 2, 4, 6, 8, 10, 11, and 13 of the '763 patent do not provide a motivation to modify the claimed sequence, and the fact that Findeis *et al.* merely discloses a couple of possible modifications to other peptides and the existence of chemical modifications to other peptide sequences does not motivate the person of ordinary skill in the art to select the presently claimed sequence and chemical modifications. This is particularly acute in the field of petidomimetics, since modification of a peptide sequence could adversely effect its function, *e.g.*, blood-brain barrier permeability and/or the ability to inhibit  $\beta$  pleated sheet formation. Therefore, the person of ordinary skill in the art, absent the present specification, is provided with no motivation to select the claimed sequence and apply the claimed chemical modifications. Reconsideration and withdrawal of the rejection are respectfully requested.

#### **Claim rejections - 35 U.S.C. § 103(a)**

Claims 12, 18, and 22-24 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Findeis *et al.* in view of Soto *et al.* (Nat Med 4(7):822-826, July 1998).

As discussed previously in regard to claims 1, 2, 4, 6, 8, 10, 11, and 13 of the '763 patent, Soto *et al.* does not provide a motivation to chemically modify the presently claimed sequence. In particular, Soto *et al.* discusses the need to test the chemical modification of a peptide (*see, e.g.*, Soto *et al.* at page 823, second column; describing chemical modification of a peptide that did not alter its ability to prevent fibrillogenesis and increased the blood-brain permeability). Further, Findeis *et al.* does not teach or suggest chemical modification of the claimed sequence, or that it would increase the stability of the claimed peptide without compromising the function *in vivo*. Since, only the present specification provides *in vivo* data demonstrating that chemical modification produces a product having increased stability and retaining activity *in vivo*, the cited

references do not provide a motivation to chemically modify the claimed sequence.

Reconsideration and withdrawal of the rejection are respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, the applicant submits that the claims define patentable subject matter and a notice of allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



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